



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

zel

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,186	04/16/2004	John Zeng Hui Zhang	57953/1221 (ZHA01-01)	8260

7590 03/23/2007
Michael L. Goldman
NIXON PEABODY LLP
Clinton Square
P.O. Box 31051
Rochester, NY 14603

EXAMINER

MORAN, MARJORIE A

ART UNIT PAPER NUMBER

1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/825,186	Applicant(s) ZHANG ET AL.	
	Examiner Marjorie Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 39-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/1/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-38 and species of protein (first molecule), drug (second molecule), CRHCOH (first cap member) and CRH₂NH₂ (second cap member) in the reply filed on 12/14/06 is acknowledged. The traversal is on the ground(s) that the groups and species are closely related and do not require separate search and consideration. This is not found persuasive because the product of Group II is not necessarily the one made/used in the method of Group I, thus the examiner maintains that the Groups are distinct. With regard to the species, each structure is a different and distinct biochemical entity, with properties different from those of any other structure. Each structure requires a different search, thus the examiner maintains that election of more than a single species for each molecule and cap member would be burdensome. Applicant is assured that upon a determination of allowability of a generic claim, all species will be rejoined and examined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 39-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/14/06. An action on the merits of claims 1-39, as they read on the elected species, follows.

Information Disclosure Statement

The IDS filed 12/1/04 has been considered in full.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See e.g., pages 6, 11, and 14. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-15 are directed to a method comprising providing and “decomposing” a molecule and introducing one or more conjugated caps to the molecule. The steps recited are not necessarily physical steps; in fact, claims 2-4 limit the providing, decomposing, and introducing steps to be electronic; i.e. to be steps performed in silico, therefore the claims do not recite a physical transformation of matter. Where a process claim does not recite a physical transformation of matter, it may be statutory if it recites a practical application; i.e. a concrete, tangible and useful result. Claim 1 recites a step of introducing molecular caps “to create a plurality of molecular portions...” but does not

recite any limitations of the molecule or caps themselves such that one skilled in the art would be apprised what the structure of the molecular portions is intended to be (i.e. the "result" is not concrete). Further, no result is output, displayed or otherwise communicated to a user in a tangible format such that the result is useful to one performing the method (i.e. the "result" is not tangible). As the claimed method does not recite a physical transformation or matter nor a concrete, tangible and useful result, the claims are not directed to statutory subject matter and are rejected.

Claims 16-26 recite a computer-readable medium comprising instructions for performing a method similar to that of claims 1-15. The computer-readable medium is not limited to be a physical medium. The specification in para 52 discloses that a computer-readable medium may be any type of media known for storing instructions, thus claims 16-26 encompass non-physical media such as satellite signals and other carrier waves. Such non-physical media are not statutory subject matter, therefore claims 16-26 are rejected.

Claims 27-38 are directed to a system comprising only "modules" or computerized instructions for carrying out method steps similar to those of claims 1-15. It is noted that the "modules" are not limited to be physical elements of the system, and that none of the claims recited any element which is necessarily physical. As the claims recite only software "molecules", they appear to be directed to a program. A program, per se, is not statutory subject matter, therefore claims 27-38 are rejected.

For further elucidation of statutory matter, see MPEP 2106, especially Section IV.

Claim Rejections - 35 USC § 112, 1st para

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

Claims 1-38 recite conjugated caps, which are not described by the specification such that one skilled in the art would be apprised of the structure intended. Para 38 discloses that each pair of caps has a first cap member and a second cap member while paragraph 40 discloses that caps are atoms or radicals that bond with a severed portion of a molecule. Neither para 38 nor Para 40 discloses what the relationship of two radicals or atoms (that bond to a severed portion) are to each other such that the two caps are considered to be "conjugated." Para 41 discloses that a first cap may be NH_3^+ and that "other caps" may be $\text{R}_n\text{C}_6\text{H}_2$. Para 41 does not disclose or exemplify what the conjugate (second cap member) which corresponds to a first cap member of NH_3^+ actually IS. Neither the Figures nor the Examples show, exemplify or otherwise describe what is intended by a "conjugated cap" such that one skilled in the art would

know what relationship caps must have to each other to be considered conjugated. As the structure of a pair of conjugated caps is not described or exemplified anywhere such that one skilled in the art would know what structures are intended and what relationship is required for "conjugated caps", the claims lack a full and complete written description and are rejected.

Claim Rejections - 35 USC § 112, 2nd para

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 9, 16, 21, 27, and 32 recite the term "conjugated caps" or "conjugated cap." The term is not defined anywhere in the specification or claims. Merriam-Webster defined "conjugated" to mean "joined together" or "having features in common but opposite or inverse in some particular" or "related by the difference of a proton" (e.g. acid/base). It is not clear which meaning of "conjugate" is intended with regard to the claimed caps. If applicant intends that the caps be joined, then it is further unclear what manner of "joining" is intended. It is noted that the specification does not provide support for any sort of "joined" pairs of molecules. If applicant intends features that are in common but opposite or inverse, then the conjugate caps may be interpreted to be structural analogs or isomers with reverse or mirror image structures. It is noted

Art Unit: 1631

that the specification does not provide support for this interpretation. If applicant intends that a "conjugate pair" be the acid and base (protonated and unprotonated) analogs of the same molecule, then it is noted that the specification does not provide support for this interpretation, either. As the intended meaning for "conjugate" with regard to "caps" is unclear, the claims are indefinite. It is noted that merely defining "cap members" as in claims 15, 26, 38, and in the election of species, does not overcome this rejection as it is still unclear what relationship between the "cap members" and/or elected species is intended in order for those members/species to be "conjugated." Claims 2-15, 17-26, and 28-38 depend directly or indirectly from one or more of claims 1, 4, 9, 16, 21, 27, and 32, and are therefore indefinite for the same reason.

Claims 1, 16, and 27 recite introducing one or more pairs of conjugated caps..at "one or more locations" in a molecule to create "molecular portions". A prior step recited decomposing the molecule into molecular fragments; however, it is unclear whether the addition of caps occurs before or simultaneously with the decomposition step. It is further unclear where in the molecule (i.e. at what locations) the conjugated caps are to be added. Thus, it is unclear whether the molecule is decomposed, then further fragmented into "portions" by the addition of caps, and/or whether the caps are added to the ends of decomposed fragments or to somewhere in the middle of each fragment such that each portion may comprise a plurality of "caps". As the intended limitation(s) are unclear, the claims are indefinite. Claims 2-15, 17-26, and 28-38 depend directly or indirectly from one or more of claims 1, 16, and 27, and are therefore indefinite for the same reason.

Art Unit: 1631

Claim 7 limits a step to comprise first and second "computing systems." A step cannot comprise a device, per se, therefore it is unclear what limitation of the step is actually intended. It is unclear whether the step is actually intended to comprise "running" a system, or performing computerized steps, or some other limitation, therefore the claim is indefinite.

Conclusion

Claims 1-38 are rejected; claims 39-44 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie Moran whose telephone number is 571-272-0720. The examiner can normally be reached on M-F 6:30 am- 2 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
3/18/07